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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/622,978	ROEHRIG ET AL.	
	Examiner	Art Unit	
	David P. Rashid	2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-2, 4-5, 7-12, 14-15, 17-23, 25-29, and 31-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 4-5, 7-12, 14-15, 17-23, 25-29, and 31-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 October 2007* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

All of the examiner's suggestions presented herein below have been assumed for examination purposes, unless otherwise noted.

Amendments

1. This office action is responsive to the claim and specification amendment received on 10/23/2007. **Claims 1-2, 4-5, 7-12, 14-15, 17-23, 25-29,** and **31-32** remain pending; **claims 3, 6, 13, 16, 24,** and **30** are cancelled.

Drawings

2. The following is a quote from 37 CFR 1.84(u)(1):

> View numbers must be preceded by the abbreviation "FIG."

3. FIG. 1 through FIG. 7 are objected to under 37 CFR 1.84(u)(1) for failing to properly abbreviate the view numbers – suggest capitalizing (e.g. "Fig. 1" to "FIG. 1")

4. The following is a quote from 37 CFR 1.84(p)(3):

> When necessary, such as indicating a surface or cross section, a reference character may be underlined and a blank space may be left in the hatching or shading where the character occurs so that is appears distinct.

5. FIG. 3 is objected to under 37 CFR 1.84(p)(3) for failing to use underlining when needed – it is suggested to underline elements 302 and 304.

6. The following is a quote from 37 C.F.R. 1.84(q):

> Lead lines are those lines between the reference characters and the details referred to. Such lines may be straight or curved and should be as short as possible. They must originate in the immediate proximity of the reference character and extend to the feature indicated. Lead lines must not cross each other. Lead lines are required for each reference character except for those which indicate the surface or cross section on which they are placed. Such a reference character must be underlined to make it clear that a lead line has not been left out by mistake. Lead lines must be executed in the same way as lines in the drawing.

7. FIG. 1 and FIG. 3 is objected to under 37 C.F.R. 1.84(q) for failing to properly use lead lines when needed –

(i) reference numeral 130 lacks a lead line – suggest adding a lead line to connect to it's proper element; and

(ii) reference numeral 306 lacks a lead line – suggest adding a lead line to connect to it's proper element.

8. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

9. In response to applicant's specification amendments and remarks received on 10/23/2007, the previous specification objections are withdrawn.

Claim Rejections - 35 USC § 101

10. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The USPTO "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (Official Gazette notice of 22 November 2005), Section IV.C, reads as follows:

> While abstract ideas, natural phenomena, and laws of nature are not eligible for patenting, methods and products employing abstract ideas, natural phenomena, and laws of nature to perform a real-world function may well be. In evaluating whether a claim meets the requirements of section 101, the claim must be considered as a whole to determine whether it is for a particular application of an abstract idea, natural phenomenon, or law of nature, rather than for the abstract idea, natural phenomenon, or law of nature itself.
>
> For claims including such excluded subject matter to be eligible, the claim must be for a practical application of the abstract idea, law of nature, or natural phenomenon. Diehr, 450 U.S. at 187, 209 USPQ at 8 ("application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection."); Benson, 409 U.S. at 71, 175 USPQ at 676 (rejecting formula claim because it "has no substantial practical application").
>
> To satisfy section 101 requirements, the claim must be for a practical application of the Sec. 101 judicial exception, which can be identified in various ways:
>
> The claimed invention "transforms" an article or physical object to a different state or thing.
>
> The claimed invention otherwise produces a useful, concrete and tangible result, based on the factors discussed below.

11. **Claims 1-2, 4-5, 7-12, 14-15,** and **17-21** are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter as follows. **Claims 1-2, 4-5, 7-12, 14-15,** and **17-21** recites the mere manipulation of data or an abstract idea, or merely solves a mathematical problem without a limitation to a practical application. A practical application exists if the *result* of the claimed invention is "useful, concrete and tangible" (with the emphasis on "result")(Guidelines, section IV.C.2.b). A "useful" result is one that satisfies the utility requirement of section 101, a "concrete" result is one that is "repeatable" or "predictable", and a "tangible" result is one that is "real", or "real-world", as opposed to "abstract" (Guidelines, section IV.C.2.b)). **Claims 1-2, 4-5, 7-12, 14-15,** and **17-21** merely manipulates data without ever producing a useful, concrete and tangible result. The steps of "processing" and "thereby

forming a[n] image" in claims 1 and 11 (as well as steps in their corresponding dependents) produce no real world result and thus lack in tangibility.

In order to for the claimed product to produce a "useful, concrete and tangible" result, recitation of one or more of the following elements is suggested:

- The manipulation of data that represents a physical object or activity transformed from outside the computer.
- A physical transformations outside the computer, for example in the form of pre or post computer processing activity.
- A direct recitation of a practical application;

Applicant is also advised to provide a written explanation of how and why the claimed invention (either as currently recited or as amended) produces a useful, concrete and tangible result.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. **Claims 1, 2, 3, 4, 5, 6, 8, 11, 12, 13, 14, 15, 16, 20** and **21** are rejected under 35 U.S.C. 102(b) as being anticipated by Giger et al. (US 5,657,362 A).

Regarding **claim 1**, Giger discloses a method for computer aided detection of medical abnormalities in x-ray medical images (Col. 1, lines 8 - 19) comprising the steps of:

processing a digital or digitized x-ray medical image (FIG. 3; FIG. 27, element 2700) to remove distinguishing effects ("after subtraction of...fat in the breast" in Col. 2, lines 53 – 56) of an x-ray device used to form said x-ray medical image (FIG. 3; FIG. 6; Col. 5, lines 48 – 65) and the effects of fat content in the object being imaged, thereby forming a processed x-ray medical image (the black areas in FIG. 6 are areas of fat removal as compared to FIG. 3); and

processing said processed x-ray medical image with a computer aided detection algorithm (FIG. 12A, elements 1205, 1206; Col. 7, lines 26 - 29) that has been optimized with a plurality of x-ray medical images that have been similarly processed with respect to the same operating parameter(s) or physical characteristic(s) ("artificial neural network trained to detect masses" OR "right and left mammograms" in Col. 7, line 20).

Regarding **claim 2**, Giger discloses the method of claim 1 wherein the x-ray medical image is a mammogram (FIG. 3; Col. 2, lines 10 - 12).

Regarding **claim 4**, Giger discloses the method of claim 1 wherein the processing removes distinguishing effects of both of the following operating parameters of the x-ray device (FIG. 27, element 2700);

x-ray energy; and

exposure.

(FIG. 3; FIG. 6B; FIG. 6D wherein the subtraction of fat pixels in binary form removes all x-ray energy, exposure, thickness of the object, and non-interesting tissue in the object being imaged.

Col. 5, lines 43 – 45 of Giger'362 incorporate the bilateral subtraction technique of Giger'020. FIG. 6; FIG. 8 of Giger'020 subtracts the features of the left breast from the right breast (or vice-versa), to strictly isolate abnormalities that is only characteristic to one breast. This will also remove x-ray energy, exposure, thickness, and non-interesting tissue of the breast image being subject to the process.).

Regarding **claim 5**, Giger discloses the method of claim 1 wherein the processing removes distinguishing effects of the following physical characteristics:

anode material;

source to image distance;

anti-scatter grid geometry;

film characteristics; and

screen-film system (FIG. 3; FIG. 6B; FIG. 6D wherein the subtraction of fat pixels in binary form remove film characteristics in the object being imaged.

Col. 5, lines 43 – 45 of Giger'362 incorporate the bilateral subtraction technique of Giger'020. FIG. 6; FIG. 8 of Giger'020 subtracts the features of the left breast from the right breast (or vice-versa), to strictly isolate abnormalities that is only characteristic to one breast. This will also remove at least the distinguishing effects of the source to image distance, film characteristics, anode material, and anti-scatter grid geometry of the breast image being subject to the process.).

Regarding **claim 8**, Giger discloses the method of claim 1 further comprising the step of further processing the processed image to form a standard form image representative of an image that would be formed at a standard x-ray energy and exposure (FIG. 8, element 804; Col. 6, lines 27 - 35).

Regarding **claim 11**, Giger discloses a method for processing x-ray medical images (Col. 1, lines 8 - 19) comprising the steps of:

processing a digital or digitized x-ray medical image (FIG. 3; FIG. 27, element 2700) of an object (FIG. 3) to remove distinguishing effects of an x-ray device used to form said x-ray medical image (FIG. 3; FIG. 6; Col. 5, lines 48 – 65) and the effects of fat content in the object being imaged ("after subtraction of...fat in the breast" in Col. 2, lines 53 – 56), thereby forming a processed x-ray medical image (FIG. 6); and

further processing the processed image to form a standard form image representative of an image that would be formed at a standard x-ray energy and exposure (FIG. 8, element 804; Col. 6, lines 27 - 35).

Regarding **claim 12**, claim 2 recites identical features as in claim 12. Thus, references/arguments equivalent to those presented above for claim 2 is equally applicable to claim 12.

Regarding **claim 14**, claim 4 recites identical features as in claim 14. Thus, references/arguments equivalent to those presented above for claim 4 is equally applicable to claim 14.

Regarding **claim 15**, claim 5 recites identical features as in claim 15. Thus, references/arguments equivalent to those presented above for claim 5 is equally applicable to claim 15.

Regarding **claim 20**, Giger discloses the method of claim 11 further comprising the step of:

processing the standard form image with a computer aided detection algorithm (FIG. 12A, element 1205; Col. 7, lines 26 – 29) that has been optimized with a plurality of x-ray medical images that have been similarly processed with respect to the same operating parameter(s) or physical characteristic(s) ("artificial neural network trained to detect masses" OR "right and left mammograms" in Col. 7, lines 26 – 29. It must be noted that the normalized processed image is the standard form image, both of which ultimately undergo the artificial neural network.).

Regarding **claim 21**, Giger discloses the method of claim 11 further comprising the step of:

processing the processed image with a computer aided detection algorithm (FIG. 12A, element 1205; Col. 7, lines 26 – 29) that has been optimized with a plurality of x-ray medical images that have been similarly processed with respect to the same operating parameter(s) or physical characteristic(s) ("artificial neural network trained to detect masses" OR "right and left mammograms" in Col. 7, lines 26 – 29).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. **Claims 7** and **17** are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination between Giger et al. (US 5,657,362 A) and Johns et al. (X-ray characterization of normal and neoplastic breast tissues, Phys. Med. Biol., 1987, Vol. 32, No. 6, 675-695).

Regarding **claim 7**, while Giger discloses the method of claim 6 wherein an x-ray image of a reference material (FIG. 1, element 102; "fat pixels" in Col. 5, lines 49 - 65) is formed at the same time as the mammogram ("original image" in Col. 5, lines 49 - 65) and under substantially the same conditions, the method further comprising the step of identifying fat content in the mammogram by comparing exposure values in the mammogram with exposure values on the x-ray image of the reference material (FIGS. 6A – 6D; Col. 5, lines 57 - 59), Giger does not teach wherein the reference material has known-x-ray attenuation characteristics representative of different percentages of fat content in the breast.

Johns discloses an x-ray characterization of normal and neoplastic breast tissue (Abstract, pg 675) wherein reference material has known-x-ray attenuation characteristics representative of different percentages of fat content in the breast (Section I. Introduction, page 676, third paragraph. Since the measuring was done on multiple patients and the fact each breast contains a distinct percentage of fat content, the x-ray attenuation characteristics are representative of different percentages of fat content in the breast.).

It would have been obvious to one of ordinary skill in the art at the time the invention was made for the method of Giger to include the reference material having known x-ray attenuation characteristics representative of different percentages of fat content in the breast as taught by Johns for "...the detection of infiltrating duct carcinomas in a fibrous breast.", Johns, Section I. Introduction, page 676, fifth paragraph in the case of single-energy imaging, and for "...imaging carcinomas with suppression of 'clutter' due to fat/fibrous contrast.", Johns, Section I. Introduction, page 676, fifth paragraph in the case of dual-energy.

Regarding **claim 17**, claim 7 recites identical features as in claim 17. Thus, references/arguments equivalent to those presented above for claim 7 is equally applicable to claim 17.

16. **Claims 9, 10, 18, 19, 26** and **27** are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination between Giger et al. (US 5,657,362 A) and Manueco Santurtun et al. (US 4,596,029 A).

Regarding **claim 9**, while Giger discloses the method of claim 8, Giger does not disclose wherein the standard x-ray energy of the standard form image representative of the image is in the range 25-28 kVp.

Santurtun discloses an x-ray generator with phase-advance voltage feedback (FIG. 2) wherein the standard ("typical") x-ray energy suggested is in the range 25-28 kVp (Col. 3, lines 3 - 14).

It would have been Santurtun to one of ordinary skill in the art at the time the invention was made for the method of Giger to include a standard x-ray energy in the range 25 – 28 kVp

for its standard form image representative of the image as taught by Santurtun for providing "...typical requirements for X-ray applications...", Col. 3, lines 5 – 6.

It must be noted that the normalization of the subtraction image will naturally bring the values of the isolated abnormalities of the processed image back into the range of the standard x-ray energy used in the original image. In essence, the x-ray energy used to create the original image will be again seen in the normalized processed image, so motivation can also arise in using a standard x-ray energy in the original image as argued above.

Regarding **claim 10**, while Giger discloses the method of claim 8, Giger does not disclose wherein the standard exposure is in the range 20 – 200 milli-Ampere-seconds.

Santurtun discloses an x-ray generator with phase-advance voltage feedback (FIG. 2) wherein the standard ("typical") exposure suggested is in the range 20 – 200 milli-Ampere-seconds (Col. 3, lines 3 - 14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made for the method of Giger to include a standard exposure in the range 20 – 200 milli-Ampere-seconds for its standard form image representative of the image as taught by Santurtun for providing "...typical requirements for X-ray applications...", Col. 3, lines 5 – 6.

Regarding **claim 18**, claim 9 recites identical features as in claim 18. Thus, references/arguments equivalent to those presented above for claim 9 is equally applicable to claim 18.

Regarding **claim 19**, claim 10 recites identical features as in claim 19. Thus, references/arguments equivalent to those presented above for claim 10 is equally applicable to claim 19.

Regarding **claim 26**, claim 9 recites identical features as in claim 26. Thus, references/arguments equivalent to those presented above for claim 9 is equally applicable to claim 26.

Regarding **claim 27**, claim 10 recites identical features as in claim 27. Thus, references/arguments equivalent to those presented above for claim 10 is equally applicable to claim 27.

17. **Claims 22, 23,** and **24** are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination between Giger et al. (US 5,657,362 A) and Saito et al. (US 5,954,650 A).

Regarding **claim 22**, while Giger discloses a method for processing mammographic images (Col. 1, lines 8 - 19) comprising the steps of:

processing a digital or digitized mammogram of a breast (FIG. 3) formed by a first mammography system of the first mammography system and fat content in the breast being imaged (FIG. 3; FIG. 6; Col. 5, lines 48 – 65), thereby forming a first processed image (FIG. 6); and

converting the first processed image into a standard-form x-ray mammogram (FIG. 3; FIG. 27, element 2700) having a first standard x-ray voltage parameter and a first standard exposure parameter (FIG. 8, element 804; Col. 6, lines 27 - 35), and

storing the standard-form x-ray mammogram (FIG. 27, element 2706), Giger does not teach whereby visual comparison of x-ray mammograms taken by different x-ray mammography systems is facilitated by comparing standard-form x-ray mammograms derived from mammograms taken by the different x-ray mammography systems.

Saito discloses a medical image processing apparatus (FIG. 1) whereby visual comparison of images (FIG. 1, element 1) taken by different imaging systems (FIG. 1, x-ray CT image, MRI image, and fusion image) is facilitated by comparing images derived from images taken by the different images systems (Col. 1, lines 6 – 14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made for the standard-form x-ray mammograms in the method of Giger to include whereby visual comparison of images taken by different imaging systems is facilitated by comparing images derived from images taken by the different images systems as taught by Saito "...to provide a strongly desired medical image processing apparatus where images of the same position with the same size, which have been imaged by modalities using different imaging methods, are superimposed on and composed with each other and are displayed so as to be able to be compared with each other realistically and visually.", Saito, Col. 1, lines 62 – 67.

Regarding **claim 23**, claim 2 recites identical features as in claim 23. Thus, references/arguments equivalent to those presented above for claim 2 is equally applicable to claim 23.

18. **Claim 25** is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination between Giger et al. (US 5,657,362 A) and Saito et al. (US 5,954,650 A), in further view of Johns et al. (X-ray characterization of normal and neoplastic breast tissues, Phys. Med. Biol., 1987, Vol. 32, No. 6, 675-695).

Regarding **claim 25**, claim 7 recites identical features as in claim 25. Thus, references/arguments equivalent to those presented above for claim 7 is equally applicable to claim 25.

19. **Claims 26-27** are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination between Giger et al. (US 5,657,362 A) and Saito et al. (US 5,954,650 A), in further view of Manueco Santurtun et al. (US 4,596,029 A).

Regarding **claim 26**, claim 9 recites identical features as in claim 26. Thus, references/arguments equivalent to those presented above for claim 9 is equally applicable to claim 26.

Regarding **claim 27**, claim 10 recites identical features as in claim 27. Thus, references/arguments equivalent to those presented above for claim 10 is equally applicable to claim 27.

20. **Claims 28-29** are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination between Johns et al. (X-ray characterization of normal and neoplastic breast tissues, Phys. Med. Biol., 1987, Vol. 32, No. 6, 675-695) and Giger et al. (US 5,657,362 A), in further view of Saito et al. (US 5,954,650 A).

Regarding **claim 28**, while Johns discloses a method for processing mammographic images (Section 2. Methods, page 676) comprising the step of:

forming in a first mammography system a digital or digitized mammogram of a breast along with images of first and second reference materials having thicknesses that range from 0 to

the thickness of the breast (Fig. 6; Section 3.4, page 689, second paragraph), one reference material having an attenuation constant that is approximately the same as that of fat (Section I. Introduction, page 676, third paragraph) and the other having an attenuation constant that is approximately the same as that of glandular tissue (Section I. Introduction, page 676, third paragraph), Johns does not teach the steps of:

(i) using exposure information in images of the first and second reference materials to process the digital or digitized mammogram system to remove substantially all effects related to the physical characteristics of the first mammography system and its operating parameters and the effect of fat content in the breast being imaged, thereby forming a first processed image;

(ii) converting the first processed image into a standard-form mammogram having pixel values that would have been obtained by a standard-form mammography system having a first standard x-ray voltage parameter and a first standard exposure parameter; and

(iii) storing said standard-form mammogram whereby

(iv) visual comparison of mammograms taken by different mammography systems is facilitated by comparing standard-form mammograms derived from mammograms taken by the different mammography systems.

Giger discloses an automated method and system for computerized detection of masses and parenchymal distortions in medical images (Col. 1, lines 8 – 19) that teaches

(i) using exposure information in the images to process the digital or digitized mammogram system (Col. 5, lines 57 - 59) to remove substantially all effects related to the physical characteristics of the first mammography system and its operating parameters (refer to

references/arguments cited in claim 4) and the effect of fat content in the breast being imaged, thereby forming a first processed image;

(ii) converting the first processed image into a standard-form mammogram having pixel values that would have been obtained by a standard-form mammography system having a first standard x-ray voltage parameter and a first standard exposure parameter (refer to references/arguments cited in claim 8); and

(iii) storing said standard-form mammogram (FIG. 27, element 2706).

It would have been obvious to one of ordinary skill in the art at the time the invention was made for the method of Johns to

(i) use exposure information in the images of the first and second reference materials of Johns to process the digital or digitized mammogram system of Johns to remove substantially all effects related to the physical characteristics of the first mammography system and its operating parameters and the effect of fat content in the breast being imaged, thereby forming a first processed image;

(ii) convert the first processed image into a standard-form mammogram having pixel values that would have been obtained by a standard-form mammography system having a first standard x-ray voltage parameter and a first standard exposure parameter; and

(iii) store said standard-form mammogram as taught by Giger "...to provide a method and system for detecting, classifying, and displaying lesions such as masses and tissue distortions in medical images such as images of the breast.", Col. 1, lines 62 – 65.

The above method of the combination of Johns in view of Giger does not teach whereby visual comparison of mammograms taken by different mammography systems is facilitated by

comparing standard-form mammograms derived from mammograms taken by the different mammography systems.

Saito discloses a medical image processing apparatus (FIG. 1) whereby visual comparison of images (FIG. 1, element 1) taken by different imaging systems (FIG. 1,x-ray CT image, MRI image, and fusion image) is facilitated by comparing images derived from images taken by the different images systems (Col. 1, lines 6 – 14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made for the standard-form mammograms in the method of the combination between Johns in view of Giger to facilitate visual comparison of images taken by different imaging systems by comparing images derived from images taken by the different images systems as taught by Saito "...to provide a strongly desired medical image processing apparatus where images of the same position with the same size, which have been imaged by modalities using different imaging methods, are superimposed on and composed with each other and are displayed so as to be able to be compared with each other realistically and visually.", Saito, Col. 1, lines 62 – 67.

Regarding **claim 29**, while the combination of Johns in view of Giger and Saito to disclose the method of 28, the combination does not teach wherein the processing removes distinguishing effects of both of the following operating parameters of the mammography system: x-ray energy and exposure.

Giger discloses an automated method and system for computerized detection of masses and parenchymal distortions in medical images (Col. 1, lines 8 – 19) that teaches wherein the processing removes distinguishing effects of both of the following operating parameters of the mammography system:

x-ray energy;

exposure (refer to references/arguments cited in claim 4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made for the combination of Johns in view of Giger and Saito to include wherein the processing removes distinguishing effects of both of the following operating parameters of the mammography system: x-ray energy and exposure as taught by Giger so that "..the number of false positives due to fat will be reduced.", Col. 5, lines 39 – 41.

21. **Claims 31** and **32** are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination between Johns et al. (X-ray characterization of normal and neoplastic breast tissues, Phys. Med. Biol., 1987, Vol. 32, No. 6, 675-695) and Giger et al. (US 5,657,362 A), in further view of Saito et al. (US 5,954,650 A) and Manueco Santurtun et al. (US 4,596,029 A).

Regarding **claim 31**, claim 9 recites identical features as in claim 31. Thus, references/arguments equivalent to those presented above for claim 9 is equally applicable to claim 31.

Regarding **claim 32**, claim 10 recites identical features as in claim 32. Thus, references/arguments equivalent to those presented above for claim 10 is equally applicable to claim 32.

Response to Arguments

22. Applicant's arguments filed on 10/23/2007 with respect to **claims 1, 8** and **11-32** have been respectfully and fully considered, but they are not found persuasive.

Summary of Remarks regarding **claims 1, 11, 22,** and **28**:

Applicant argues that the claims as amended distinguish over Giger. In particular, while Giger discloses various processing techniques, she does not disclose or suggest processing the x-ray image so as to remove from the image the effects of fat content in the object being imaged. Since the rejection of all of the claims is based in whole or in part on Giger, it is submitted that all of the claims, as amended, are patentable over the reference cited (*@ response page 9*).

Examiner's Response regarding **claims 1, 11, 22,** and **28**:

Giger et al. (US 5,657,362 A) discloses processing the x-ray image so as to remove from the image the effects of fat content in the object being imaged by the act of subtracting of the fat in the breast (Col. 2, lines 53 – 56; differences between FIG. 6 and FIG. 3). All of the claims, as amended, are not patentable over the reference cited as indicated above.

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Summary of Remarks regarding **claims 8** and **11 – 32**:

Applicant argues claims 8 and 11-32 further distinguish over Giger, for example, in their recitation of the step of forming a standard form image. These claims all require the formation of an image representative of the image that would be formed at a standard x-ray energy and exposure. Giger does not disclose or suggest such a step in her disclosure in FIG. 8 of a normalization step 804. As indicated at Col. 6, lines 30-32, this step merely normalizes an image so that its average gray level matches the average gray level of the original image. No suggestion

is made of applicants' claimed step of forming an image representative of the image that would be formed at a standard x-ray energy and exposure (*@ response pages 9-10*).

Examiner's Response regarding **claims 8** and **11 – 32:**

Normalization is any process that makes something more normal, which means returning from some state of abnormality. Giger does in fact disclose "normalization" of the breast digital image when the averaged gray level matches the average gray level of the original image. The average gray level of the original image is the "normal condition" from which the image under analysis (which is away from the average gray level of the original image, and thus "some state of abnormality) returns to the average gray level of the original image. The original image was formed at a standard x-ray energy and exposure to produce a specific average gray level. The image under analysis that is normalized again reverts back to the same specific average gray level, and thus the standard x-ray energy and exposure of the original image as well.

Summary of Remarks regarding **claims 22-32**:

Applicant argues claims 22-27, as amended, further define over Giger and Saito in that they are now limited to comparisons of mammograms formed by x-ray mammography systems. Saito discloses methods of comparing images from different types of mammography systems such as x-ray, MRI, etc.

Claims 28-32 further define over Johns in that they require the use of two reference materials having thicknesses that range from 0 to the thickness of the breast. One reference material has an attenuation that is approximately the same as that of fat and the other an attenuation approximately the same as that of glandular tissue. While Johns may disclose the use

of reference materials he does not disclose or suggest the use of such materials with a range of thicknesses.

Further, it is respectfully submitted that the references do not suggest their combination to provide the methods recited by the claims.

For the foregoing reasons, the claims as amended are believed to be patentable over the references (*@ response page 10*).

Examiner's Response regarding **claims 22-32**:

However, applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Conclusion

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David P. Rashid whose telephone number is (571) 270-1578. The examiner can normally be reached Monday - Friday 8:30 - 17:00 ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vikkram Bali can be reached on (571) 272-7415. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David P. Rashid/
Examiner, Art Unit 2624

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Examiner
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